1

METHOD AND APPARATUS FOR DETECTING CHANGE IN INTRATHORACIC ELECTRICAL IMPEDANCE

RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 13/177,912, filed Jul. 7, 2011, which claims priority and other benefits from U.S. Pat. No. 7,986, 994, filed Dec. 3, 2003, which claims priority and other benefits from U.S. Provisional Patent Application Ser. No. 60/430,983, filed Dec. 4, 2002, entitled "METHOD AND APPARATUS FOR DETECTING CHANGES IN INTRATHORACIC ELECTRICAL IMPEDANCE", each incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

The present invention generally relates to implantable medical devices, and in particular, the present invention ²⁰ relates to impedance monitoring in an implantable medical device to determine physiological conditions in a patient.

BACKGROUND OF THE INVENTION

Impedance monitoring has been used for determination of numerous physiologic conditions within the body with implanted devices and has been used in external monitoring devices as well. It is commonly understood that transthoracic impedance measurements give a good indication of the fluid 30 status of patients, with decreases in impedance being indicative of increases in fluid content. In an article entitled "Transthoracic Electrical Impedance as a guide to Intravascular Overload" by Berman et. al. (Archives surgery, V102 P61-64 January 1971), electrical impedance methods were used to 35 document the accumulation of fluid in the living tissue. Knowledge of a patient's long-term impedance measurement and changes therein is a valuable clinical indicator of a patient's health, which has heretofore been unavailable to physicians in a very useful form.

While a possible indication of other conditions, the accumulation of fluid can also be an indication of failing heart circulation. There are several mechanisms or diseases that can cause or affect the accumulation of fluid. In general, fluid accumulation is a failure or over response of the homeostatic 45 process within the body. The body normally prevents the build up of fluids by maintaining adequate pressures and concentrations of salt and proteins, and by actively removing excess fluid. Fluid accumulation can occur, for example, when the body's mechanisms for preventing fluid accumula- 50 tion are affected by disease, such as heart failure, left sided myocardial infarction, high blood pressure, altitude sickness, emphysema (all which affect pressures), cancers that affect the lymphatic system, diseases which disrupt the protein concentrations, and so forth. As a result, providing an adequate 55 monitor of the patient's fluid status can provide physicians and patients with a better tool to manage disease.

It has been demonstrated, for example, in the article "EFFECTS OF PREHOSPITAL MEDICATIONS ON MORTALITY AND LENGTH OF STAY IN CONGESTIVE 60 HEART FAILURE," by Wuerz and Meador, ANNALS OF EMERGENCY MEDICINE, 21:6, June, 1992, pp 669-74, that early pre-hospital treatment for congestive heart failure can save lives. Unfortunately, the first indication that a treating physician would ordinarily have of the occurrence of the accumulation of fluids occurs very late in the disease process with the physical manifestation of swelling or breathing dif-

2

ficulties so overwhelming as to be noticed by the patient who then most often proceeds directly to an emergency room and to hospital admission for fluid overload. On the other hand, with current efforts to reduce the number and length of hospital stays, proactive hospitalization simply to monitor a patient's progression of fluid accumulation is generally not desirable.

Recent attempts at improving more frequent assessment of fluid status without requiring hospital stays are illustrated in the articles "ELECTRONIC HOME MONITORING OF CONGESTIVE HEART FAILURE PATIENTS: DESIGN AND FEASIBILITY", by Baer, CA, DiSalvo TG, Cail MI, Noyes D, and Kvedar J C, Congest Heart Fail. 1999; 5:105-113, and "COMPLIANCE AND EFFECTIVENESS OF 1 YEAR'S HOME TELEMONITORING", by deLusignan S, Wells S, Johnson P, Meredith K, and Leatham E, Eur J Heart Fail. 2001; 3: 723-30, which suggest assessment of fluid status being done daily in the home by the patient, using heart failure scales that measure the patient's weight and instruct the patient to answer a number of questions each day. Although this concept may in fact reduce CHF hospitalizations, daily patient compliance is required and the assessment has to be done in the patient's home, making travel by the patient difficult.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages and features of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 is a schematic diagram of an implantable medical device according to an embodiment of the present invention;

FIG. 2 is a schematic diagram of exemplary electrode configurations in an implantable medical device according to an embodiment of the present invention;

FIG. 3 is a schematic diagram of an exemplary implantable medical device in which the present invention may usefully be practiced;

FIG. 4 is a schematic diagram of a monitoring circuit included in an exemplary implantable medical device in which the present invention may usefully be practiced;

FIG. 5 is a graphical representation of a timing sequence utilized in the monitoring circuit of FIG. 4 according to an embodiment of the present invention;

FIG. 6 is a schematic diagram of an implantable medical device in which the present invention may usefully be practiced according to an embodiment of the present invention;

FIG. 7 is a functional block diagram of an exemplary implantable medical device of the type illustrated in FIG. 6, in which the present invention may usefully be practiced;

FIG. 7A is a schematic diagram of a method of measuring impedance according to an embodiment of the present invention:

FIG. 8 is a graphical representation of impedance data generated according to an embodiment of the present invention:

FIG. **8**A is an exemplary graphical representation of impedance data generated according to an embodiment of the present invention;

FIG. 9 is a flow chart illustrating a method for determining changes in impedance according to an embodiment of the present invention;